FDA Center for Tobacco Products Update
(June 22 –September 30, 2011)

The FDA Center for Tobacco Products (CTP) intends to provide regular updates to inform the public and Congress on its progress in implementing the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). This summary does not reference all actions taken by CTP.

September 2011

State Enforcement Program Update

In the summer of 2010, FDA established the CTP State Enforcement Program and began awarding FY2010 contracts to states and territories to assist with inspections of retail establishments to help enforce the Youth Access and Advertising Regulations of the Tobacco Control Act that took effect on June 22, 2010. During the first year, tobacco retail inspection contracts were awarded to 15 states. These 15 states conducted inspections of retail establishments in their states throughout FY2011, and by the end of September they had completed more than 25,000 inspections which resulted in the issuance of more than 1,000 warning letters to retailers who were found to be in violation of the new law. Also throughout FY2011, FDA continued to award or re-award contracts to states and territories. By September 30, 2011, a total of 38 new contracts were awarded to states and the District of Columbia.

- Tobacco Retailer Warning Letters

Tobacco Retail Inspection Contracts: September

In September 2011, FDA awarded or re-awarded contracts to the following states to assist FDA with conducting compliance check inspections of retailers: Alabama, Arizona, Arkansas, California, Georgia, Hawaii, Iowa, Kansas, Louisiana, New Hampshire, New Mexico, North Carolina, Ohio, Oklahoma, Utah, and Washington. A current list of tobacco retail inspection contracts can be found on the CTP website.

- States Awarded FDA Tobacco Retail Inspection Contracts

Stakeholder Discussion Series Session with Youth

On September 13, 2011, CTP hosted a Stakeholder Discussion Series session with youth in Boston, MA to provide an opportunity to get their perspective on FDA's implementation of the Tobacco Control Act, to establish good lines of communication and productive working relationships between CTP and youth, and to learn more about their ideas, issues, and concerns.

- Youth Discussion Information
- Stakeholder Discussion Series

Draft Guidance on Premarket Tobacco Product Applications

On September 27, 2011, FDA issued a draft guidance to help persons submitting applications for new tobacco products understand the premarket tobacco product application process. The draft guidance addresses questions such as who may submit a new tobacco product application, when to submit one, what the legal requirements are, and what FDA recommends for those submitting a new tobacco product application. The 90-day public comment period will be open until December 27, 2011.

Providing comments on draft guidances is an opportunity for all stakeholders and the general public to be part of the regulatory process. FDA carefully considers comments when writing the final guidance. The most useful comments provide suggested alternative language and/or provide data to support the positions taken.

- Draft Guidance: Applications for Premarket Review of New Tobacco Products

Webinar Series for Tobacco Retailers and Small Manufacturers

CTP continued its series of one-hour webinars designed to provide tobacco retailers with information on how to comply with federal tobacco regulations. Webinars were held in May, June, July, and September on various topics, including graphic health warnings for cigarettes, smokeless tobacco product packages and advertising, non-face-to-face sales, the prohibition against breakage of cigarette and smokeless tobacco packages, minimum cigarette package size, and distribution of free samples. CTP's Office of Small Business Assistance also hosted a webinar on July 26, 2011, designed specifically for small tobacco manufacturers, importers, and distributors on how to comply with the new graphic health warnings for cigarettes. All webinars in this series are archived on the CTP website.

- FDA Tobacco Compliance Webinars - Education and Information for Retailers and Small Businesses
- Archived Tobacco Compliance Training
- FDA Tobacco Compliance Webinars - Email Updates

Proposed Rule on Non-Face-to-Face Sale and Distribution of Tobacco Products

FDA posted an advance notice of proposed rule making (ANPRM) on September 9, 2011, to obtain information related to the regulation of non-face-to-face sale and distribution of tobacco products and the advertising, promotion, and marketing of tobacco products. The public comment period will be open until December 8, 2011.

- Proposed Rule: Non-Face-to-Face Sale and Distribution of Tobacco Products and Advertising, Promotion, and Marketing of Tobacco Products

Draft Guidance on Warning Plans for Cigarettes and Smokeless Tobacco

On September 9, 2011, FDA published a draft guidance intended to assist persons submitting warning plans for cigarettes and warning plans for smokeless tobacco products. The public comment period will be open until November 8, 2011.

- Draft Guidance: Submission of Warning Plans for Cigarettes and Smokeless Tobacco Products

Draft Guidance on Substantial Equivalence Frequently Asked Questions

FDA published a draft guidance on September 9, 2011, to provide information in response to frequently asked questions that CTP received from manufacturers and other interested stakeholders on demonstrating the substantial equivalence of a new tobacco product. Topics include labels and packaging, product names, additives, and general questions about substantial equivalence reports. The public comment period will be open until November 8, 2011.

- Draft Guidance: Demonstrating Substantial Equivalence of New Tobacco Product; Responses to Frequently Asked Questions

Research Studies

FDA funded three research projects via interagency agreements with the National Institutes of Health.

1. The Population Assessment of Tobacco and Health (PATH) Study is a national, longitudinal cohort study of more than 40,000 users of tobacco products and those at risk for tobacco use ages 12 and older in the U.S. Results from this study will assess the impact of FDA regulatory authority over tobacco products and provide information to help inform future activities such as establishing product standards and communicating risks of tobacco use. The PATH study is being conducted in collaboration with the National Institute on Drug Abuse (NIDA) via a contract from Westat.
2. CTP funded a NIDA Centers of Excellence research grant to evaluate nicotine in cigarettes. The aim of this research project is to evaluate the dose-response relationship for nicotine yield within the range thought to be at or below the threshold for dependence, to assess the effects of prolonged use of very low nicotine content cigarettes comparing immediate switching with gradual reduction, to assess viability in smokers with schizophrenia, and to assess the reinforcing effects of nicotine within the context of other components of cigarette smoke.
3. CTP funded a National Cancer Institute research project grant that will conduct real-time measurement and uptake of carcinogens by menthol cigarette smokers. The aim of this study is to develop procedures for evaluating acute, within-subject toxicant exposure and other smoke characteristics of cigarettes with varying levels of menthol and to generate data relevant to the understanding of potential health effects of menthol as a cigarette additive.

August 2011

Tobacco Retail Inspection Contracts: August

In August 2011, FDA awarded or re-awarded tobacco retail inspection contracts to nine states: Colorado, Illinois, Indiana, Michigan, Missouri, Tennessee, Texas, Virginia, and West Virginia.

- States Awarded FDA Tobacco Retail Inspection Contracts

Public Workshop on Modified Risk Tobacco Product (MRTP) Applications

FDA hosted a public workshop on August 25 and 26, 2011, at FDA headquarters in Silver Spring, MD to discuss issues pertinent to the scientific evaluation of modified risk tobacco product (MRTP) applications. The workshop was designed so that FDA could receive input from a variety of experts on what scientific studies would help demonstrate that a MRTP reduces harm or risk of tobacco-related disease. A docket was open for public comment from June 22 – September 23, 2011. CTP uses public dockets through the *Federal Register* to solicit information from all stakeholders on a number of issues related to the implementation of the Tobacco Control Act.

- Public Workshop: Scientific Evaluation of Modified Risk Tobacco Product (MRTP) Applications
- Federal Register Notice of Public Workshop

Stakeholder Discussion Series Session with Distributors, Importers, Retailers, and Wholesalers

On August 24, 2011, CTP hosted a Stakeholder Discussion Series session in Dallas, TX with tobacco distributors, importers, retailers, and wholesalers to discuss common interests, ways to enhance communication, and priority issues of interest for future discussion. A meeting summary and other meeting materials are available on the CTP website.

- Distributors, Importers, Retailers, and Wholesalers Discussion Information
- Stakeholder Discussion Series

Docket for Public Comment on Harmful and Potentially Harmful Constituents

On August 12, 2011, FDA opened a docket to solicit scientific and other information related to harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke. FDA is particularly interested in comments from the public on the criteria FDA should use in determining a constituent's inclusion on the HPHC list and whether any constituents should be added to or removed from its current draft list, including supporting scientific or other information. The docket closed on October 11, 2011.

- Request for Comments: Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke

July 2011

Tobacco Retail Inspection Contracts: July

In July 2011, FDA awarded or re-awarded tobacco retail inspection contracts to seven states: Connecticut, Delaware, New Jersey, Maryland, Mississippi, Washington, D.C., and Wisconsin.

- States Awarded FDA Tobacco Retail Inspection Contracts

Tobacco Products Scientific Advisory Committee (TPSAC) Meeting

The Tobacco Products Scientific Advisory Committee (TPSAC) met on July 21 and 22, 2011, to provide clarifying and conforming edits to the TPSAC Menthol Report, which was originally submitted to FDA on March 18, 2011, and to initiate discussions on the nature and impact of the use of dissolvable tobacco products on the public health.

- Background Materials for Menthol Session – July 21, 2011
- Background Materials for Dissolvables Session – July 21-22, 2011
- Archived Webcasts – July 21-22, 2011

Submission of FDA Science Report to Peer Review Panel

FDA submitted its draft independent review of the science related to the impact of menthol in cigarettes on public health to an external peer review panel in July 2011. After peer review, the agency will make the results of the peer review and the preliminary scientific assessment available for public comment in the *Federal Register*.

Final Regulations on Exemptions from Substantial Equivalence Requirements

On July 5, 2011, FDA issued a final rule that describes the process and statutory criteria for requesting an exemption from the substantial equivalence requirements for a new tobacco product and explains how FDA reviews requests for exemptions. The final rule implements the exemption provision of the Tobacco Control Act and reflects FDA's consideration of the comments received on the January 2011 proposed rule.

- Final Rule – Exemptions from Substantial Equivalence Requirements for Tobacco Products

June 2011

Tobacco Retail Inspection Contracts: June

In June 2011, FDA awarded or re-awarded tobacco retail inspection contracts to six states: Kentucky, Maine, Massachusetts, Minnesota, Pennsylvania, and Rhode Island.

- States Awarded FDA Tobacco Retail Inspection Contracts

Stakeholder Discussion Series Session with American Indians/Alaska Natives

On June 28, 2011, CTP hosted a Stakeholder Discussion Series session in Phoenix, AZ with American Indians/Alaska Natives to discuss common interests, coordination and communication, and issues of interest for future discussion. A meeting summary and other meeting materials are available on the CTP website.

- American Indians/Alaska Natives Discussion Information
- Stakeholder Discussion Series

90-Day Menthol Update

On June 27, 2011, approximately 90 days after the due date of the TPSAC menthol report, FDA provided its first progress report regarding its review of the public health impact of menthol in cigarettes. The 90-day update states that experts within FDA are conducting an independent review of the available science including peer-reviewed literature, secondary data analyses, and independent CTP analyses of relevant large data sets.

- Menthol Update